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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,904	02/20/2002	Hiroyuki Miyachi	219217US0PCT	2368

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EXAMINER

ANDERSON, REBECCA L

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 05/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/049,904

Applicant(s)

MIYACHI ET AL.

Examiner

Rebecca L Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 11-22 is/are pending in the application.
- 4a) Of the above claim(s) 11-19 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 20 and 21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 1-7 and 11-22 are currently pending in the instant application. Claims 1-7, 20 and 22 are rejected and 11-19 and 21 are withdrawn from further consideration.

Election/Restrictions

Newly submitted claims 11-19 and 21 directed to inventions that are independent or distinct from the invention originally claimed for the following reasons: Claims 11-19 are drawn to methods of use for the benzylthiazolidine-2,4-dione compounds as found in claim 1 and claim 21 is drawn to the process for the preparation of products of the compounds as found in claim 1. The current invention of claims 1-7, 20 and 22, product claims, are related to the claims 11-19 as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product such as the compounds found in US Patent No. 5,223,522 which are blood glucose lowering agents. The current invention of claims 1-7, 20 and 22, product claims, are related to the claim 21 as product and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make other and

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materially different products such as those products as found in U.S. 5,223,522.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 11-19 and 21 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Amendment and Arguments

Applicants amendment filed 28 February 2003 has been considered and entered as Paper No. 9. Applicants cancellation of claims 8-10 has overcome the objection and rejection under 35 U.S.C. 112 to these claims. Applicants amendment to claim 1 has overcome the 35 U.S.C. 112 rejection of claim 1. Applicant's arguments with respect to the rejection of claims 1-10 under 35 U.S.C. 103(a) have been considered but are moot in view of the new ground(s) of rejection. In addition to applicants arguments and amendments, applicant has also provided a comparative data study, Exhibit A, which is a set of experiments comparing the efficacy of the compounds 17, 22, 23 and 28 disclosed by EP'693 with compounds 1-3 of the claimed invention. It is noted that this set of comparative data would be considered an effective showing of unobvious results and would overcome the new 35 U.S.C 103(a) rejection if presented in correct declaration form under 37 C.F.R. 1.132.

Specification

The amendment filed 28 February 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no

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amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: a suitable carrier claimed in claims 20 and 22 is not supported by the original disclosure.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Newly added claims 20 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 20 and 22 are composition claims that contain the phrase "a suitable carrier." However, this subject matter was not described in the specification in any way. The only description found in the specification that closely relates to the a suitable carrier was the description on page 8 which relates to the administration of the compounds of the invention, however this description is silent to the possible suitable carriers. It is suggested that these claims be cancelled to overcome this rejection and the objection to the amendment above.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

Claims 1-7, 20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 846 693 in view of US Patent No. 5,061,717.

The claims at issue teach benzylthiazolidine-2,4-dione products of the formula (1) as found in claim 1 wherein A denotes a phenyl, phenoxy, or benzyloxy group. These products can be used as blood glucose-decreasing drugs, lipid in blood-decreasing drugs and as agonists of human peroxisome proliferator-activated receptors.

Determining the scope and contents of the prior art.

EP 0 846 693 discloses benzyldioxothiazolidylbenzamide compounds of the formula (I) which are useful for the treatment of diabetes and hyperlipidemia (page 2, lines 1-6). The compound of formula (I) is substituted by R1, R2 and R3. R1 and R2 can be hydrogen, lower alkyl, lower alkoxy, lower haloalkyl, etc., while R3 can be lower alkoxy, hydroxyl or halogen atom. The dotted line indicated a double or a single bond (page 2 lines 30-46). Furthermore, EP 0 846 693 discloses specific compounds wherein the dotted line is a single bond, and R3 is **methoxy** (compound examples 17 where R1 is 3-CF₃, 19 where R1 is 2-CF₃, 22 where R1 is 4-t-Bu and 26 where R1 is 4-MeO in Table 5, pages 12-13).

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US Patent No. 5061717 discloses thiazolidinedione compounds of the formula (I) wherein X1 and X2 can be hydrogen, methyl, trifluoromethyl, **phenyl**, benzyl, hydroxy, methoxy, **phenoxy**, **benzyloxy**, etc. (column 3 lines 60-67 and column 4 lines 1-21). X2 is preferably hydrogen, and X2 is preferably hydrogen, 2-methoxy, 4-benzyloxy or 4-phenyl. A and B can be CH or N, preferably CH. X can be S, SO, CH2, CO, preferably CO. Z can be CHR3, Y can be NR2, n can be 1, and R is preferably hydrogen and the dotted line represents no bond (column 4, lines 1-27). These compounds are useful as blood glucose lowering compounds for the treatment of hyperglycemia (column 4, lines 50-63). US Patent No. 5061717 furthermore discloses specific compounds in the table found on column 19 wherein X2 is **benzyloxy** (#46) and **phenyl** (#48b), and US Patent NO. 5061717 discloses the specific compound of example #75 on column 24 wherein X2 is **phenoxy**.

Ascertaining the differences between the prior art and the claims at issue.

The difference between the prior art of EP 0 846 693 and the claims at issue is that in the position equivalent to applicant's substituent A, the prior art does not have phenyl, phenoxy, or benzyloxy.

The difference between the prior art of US Patent No. 5061717 and the claims at issue is that there is no methoxy substituent on the benzamide ring and the compounds are positional isomers of the compounds as instantly claimed

Resolving the level of ordinary skill in the pertinent art.

However, minus the showing of unobvious results, it would have been obvious to one of ordinary skill in the art at the time of the invention when faced with EP 0 846 693 and US Patent No. 5,061,717 to create products which are useful for the treatment of as

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glucose lowering drugs, wherein A is benzyloxy, phenoxy or phenyl and the benzylthiazolidine-2, 4-dione is substituted by methoxy, due to the similar chemical structure (benzylthiazolidine-2, 4-dione) of the compounds of the prior art, which is seen in the disclosure of US Patent No. 5,061,717 that discloses benzyloxy, phenoxy and phenyl as substituents on a benzylthiazolidine-2, 4-dione useful as blood glucose lowering agents. The reasoning behind the finding of obviousness is that U.S. Patent No. 5,061,717 discloses the interchangeability of the substituents benzyloxy, phenoxy or phenyl (X1 and X2, which can also be hydrogen, methyl, trifluoromethyl, etc.) with R1 and R2 or EP 0 846 693 wherein R1 and R2 are H lower alkyl, lower haloalkyl, etc. on the benzylthiazolidine-2,4-diones useful as blood glucose lowering agents and therefore one would be motivated to prepare compounds as found in EP 0 846 693, which are substituted with methoxy, with the substituents benzyloxy, phenoxy or phenyl when faced with US Patent No. 5,061,717 which are useful benzylthiazolidine-2,4-dione compounds as blood glucose lowering drugs. Consequently, the motivation to prepare compounds as found in EP 0 846 693, which are substituted with methoxy, with benzyloxy, phenoxy or phenyl substituents would be to create other useful benzyldioxothiazolidylbenzamide compounds useful as blood glucose lowering drugs.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (703) 605-1157. Mrs. Anderson can normally be reached Monday through Friday 7:00AM to 3:30PM.

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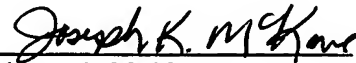
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone numbers are (703) 308-1235 and (703) 308-0196.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45AM to 4:45PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4242, (703) 305-3592, and (703) 305-3014.



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